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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,630	05/30/2006	Kari Alitalo	28113/39467A	2853

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EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	**PAPER NUMBER**
1642	
MAIL DATE	**DELIVERY MODE**
07/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,630	ALITALO ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/10/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-15, 17, 21, 22, 25-29, 31, 33, 34, 36-38, 41, 46, 48, 52,

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-15,17,21,22,25-29,31,33,34,36-38,41,46,48,52,54,55,68 and 70-76.

DETAILED ACTION

Applicant's election of 04/10/09 is acknowledged.

After review and reconsideration, the restriction requirement of 12/10/08 is withdrawn, and replaced with the following new restriction requirement.

In a telephonic conversation with the Attorney David Gass on 07/20/09, Applicant declines telephonic election and prefers a written restriction requirement.

Claims -15, 17, 21, 22, 25-29, 31, 33, 34, 36-38, 41, 46, 48, 52, 54, 55, 68, and 70-76 are pending and are subjected to the following restriction requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-6, 11-14, 79, drawn to a method for detecting a pathology of colon, or colon cancer, by detecting the level or activity of Prox-1 protein.

Group 2, claim(s) 1-4, 7-14, 79, drawn to drawn to a method for detecting pathology of colon, or colon cancer, by detecting the level of Prox-1 nucleic acid.

Groups 3-12, claim 15, drawn to a combination of a method for detecting a pathology of colon, or colon cancer, by detecting the level or activity of Prox-1 protein, and a method for

treating colon pathology or cancer, using an inhibitor of Prox-1, which is an antibody to Prox-1 protein, an antisense to Prox-1 nucleic acid, a micro-RNA, an siRNA, a short hairpin RNA, a zinc finger protein, a dominant negative Prox-1 protein, the encoding nucleic acid thereof, an inhibitor of DNA methyltransferase protein, or an inhibitor of DNA methyltransferase nucleic acid. A combined method of detecting a pathology of colon, or colon cancer, and a method for treating said pathology or colon cancer, using each of the above inhibitor of Prox-1 protein or nucleic acid constitutes a single, distinct invention, and not a species.

Groups 13-22, claim 15, drawn to a combination of a method for detecting a pathology of colon, or colon cancer, by detecting the level of Prox-1 nucleic acid, and a method for treating colon pathology or cancer, using an inhibitor of Prox-1, which is an antibody to Prox-1 protein, an antisense to Prox-1 nucleic acid, a micro-RNA, an siRNA, a short hairpin RNA, a zinc finger protein, a dominant negative Prox-1 protein, the encoding nucleic acid thereof, an inhibitor of DNA methyltransferase protein, or an inhibitor of DNA methyltransferase nucleic acid. A combined method of detecting a pathology of colon, or colon cancer, and a method for treating said pathology or colon cancer, using each of the above inhibitor of Prox-1 protein or nucleic acid constitutes a single, distinct invention, and not a species.

Group 23, claims 17, 21, 31, 33-34,36-38, 41, 46, drawn to a method for treating colorectal cancer, using an antibody to Prox-1 protein.

Groups 24-28, claims 17, 21-22, 25, 31, 33-34, 36-38, 41, 46, 68, 70-73, 76, drawn to a method for treating colorectal cancer, using an inhibitor of Prox-1 nucleic acid, which is an antisense to Prox-1 nucleic acid, a micro-RNA, an siRNA, a short hairpin RNA, or a zinc finger

protein. A method for treating colorectal cancer, using each of the inhibitor of Prox-1 nucleic acid constitutes a single, distinct invention, and not a species.

Groups 29-30, claims 17, 21, 27-29, 31, 33-34, 36-38, 41, 46, drawn to a method for treating colorectal cancer, using an inhibitor of Prox-1, which is a dominant negative Prox-1 protein, or the encoding nucleic acid thereof. A method for treating colorectal cancer, using each of the inhibitor of Prox-1 constitutes a single, distinct invention, and not a species.

Group 31, claims 17, 31, 33-34, 36-38, 41, 46, 74-75, drawn to a method for treating colorectal cancer, using an inhibitor of DNA methyltransferase protein.

Group 32, claims 17, 31, 33-34, 36-38, 41, 46, 74-75, drawn to a method for treating colorectal cancer, using an inhibitor of DNA methyltransferase nucleic acid.

Group 33, claims 48, 52, drawn to a method for screening a modulator of Prox-1 protein.

Group 34, claims 48, 52, drawn to a method for screening a modulator of Prox-1 nucleic acid.

Group 35, claims 54-55, drawn to a combined method of screening a modulator of Prox-1 protein, that binds to Prox-1 protein, and a method for treating colorectal cancer, using said modulator of Prox-1 protein, which is an antibody to Prox-1 protein.

Groups 36-40, claims 54-55, drawn to a combined method of screening a modulator of Prox-1 nucleic acid, that binds to Prox-1 nucleic acid, and treating colorectal cancer, using said modulator of Prox-1 nucleic acid, which is an antisense to Prox-1 nucleic acid, a micro-RNA, an siRNA, a short hairpin RNA, or a zinc finger protein. A combined method for screening a modulator of Prox-1 nucleic acid, and treating colorectal cancer, using each of the inhibitor of Prox-1 nucleic acid constitutes a single, distinct invention, and not a species.

In addition, Groups 1-2 are subjected to the following patentably distinct **species** of the claimed invention:

Measuring the expression or activity of CD44, Enc1, ID2, or activation of beta-catenin/TCF pathway.

Upon election of the species activation of beta-catenin/TCF pathway, further following species election is required:

Mutation of an APC gene, mutation of a beta-catenin gene, or nuclear localization of beta-catenin.

Groups 16, 26, 38 are also subjected to the following patentably distinct species of the claimed invention:

SiRNA of SEQ ID NO: 4, 5, 6 or 7.

Groups 23, 29-32 are also subjected to the following patentably distinct species of the claimed invention:

Further administration of a Notch signaling agonist, an inhibitor of the beta-catenin/TCF signaling pathway, or a Cox-2 inhibitor.

Groups 24-28 are also subjected to the following patentably distinct species of the claimed invention:

Further administration of a Notch signaling agonist, an inhibitor of the beta-catenin/TCF signaling pathway, a Cox-2 inhibitor, an inhibitor of DNA methyltransferases.

Upon election of the species inhibitor of beta-catenin/TCF pathway, further following species election is required:

TCF-4, beta-catenin, or c-myc.

The inventions are distinct, each from the other because of the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as groups 1-40 do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of the claimed invention, Prox-1, is known in the art, as disclosed in the specification, on page 1, for example, Wigle et al., Nat. Genet. 21: 318-22, 1999, Sosa-Pineda et al., Nat. Genet. 25: 254-5, 2000, or Wigle et al., Cell 98: 769-778, 1999. The methods of groups 1-40 are different methods of use of Prox-1, and are distinct from each other, because they do not share common objectives, and/or use different composition, which do not share common structure and properties. The different species are distinct, because they do not share common structure and properties.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted, even though the requirement be traversed (37 CFR 1.143).

If any one of groups 1-2, 16, 26, 23-32, 38 were elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits, and a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
July 28, 2009

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643